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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,783	05/16/2000	NEIL P. DESAI	VPHAR1460-2	2878

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EXAMINER
HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
1616	24

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/446,783	Applicant(s) DESAI ET AL.	
	Examiner Michael G. Hartley	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-35,46-67 and 70-120* is/are pending in the application.

4a) Of the above claim(s) *29-35,46-67,70-72,76-100 and 109-120* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-75 and 101-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Applicant's election with traverse of Group 15 in Paper No. 23 is acknowledged. The traversal is on the ground(s) that the claims have divided into an excessive number of groups. This is not found persuasive because the number of groups corresponds to the distinct inventions set forth in the claims. There are many claims presented in the application, with approximately 18 independent claims, which have different and divergent limitations, as some claims require mechanical parts, such as tubing, etc., while others are directed to methods that require administration of a drug at a certain rate, or without the use of a filter, while other groups require liquid formulations, other groups require dry powders with a protein and some are defined functionally. The distinct and divergent subject matter in the claims would be unduly burdensome to search and examine. Applicant's argument of an excessive number of groups is not found persuasive as the number of groups depends on the claims presented, and excessive is a relative term which is dependent on the number of invention presented. It is noted that claim 72 was mistakenly listed in Group 15; however, this claim is dependent on claim 71 (Group 14) and is not directed to the elected invention of Group 15 (a dry powder comprising a protein), as claim 72 (or 71) has no protein. Thus, the elected group includes claims 73-75 and 101-108.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 73-75, 101-104, 107 and 108 are rejected under 35 U.S.C. 102(b) as being anticipated by Desai (US 5,439,686).

Desai discloses compositions comprising a protein that contain "particles of taxol" see abstract. Particles of taxol are prepared in example 1 and are most preferably less than 1 micron, which encompasses nanoparticles. Exemplified proteins are albumin and the drug is taxol, see column 6, lines 35+ and examples 2, 4 and 9. The particle size includes 0.1 microns, which is 100 nm, see column 9, lines 15-16. The particles are for paternal administration, see column 3.

Claims 73-75, 101-104 and 106-108 are rejected under 35 U.S.C. 102(e) as being anticipated by Yen (US 5,945,033).

Yen discloses an article of manufacture comprising a dry powder or liquid formulation of a drug and at least one protein, wherein the formulation comprises drug nanoparticles. Yen discloses proteins (i.e., hemoglobin or albumin) particles as drug carriers (clot dissolving agents) which have particle sizes of about 0.1 microns, or 100 nm, see column 26, lines 16-28. The compositions include dry and aqueous formulations which are for injection, see column 18, lines 9+. Yen disclose that various drugs may be used, including a taxane (taxol), as well as, thyroid hormone, etc., see column 46, line 52 and column 38, line 24. While Yen teaches that a surfactant may be employed, this is only a optional embodiment, and no surfactant is required, see column 4, lines 49+

Claims 73, 102, 103, 107 and 108 are rejected under 35 U.S.C. 102(e) as being anticipated by Friedman (US 5,897,879).

Friedman discloses an article of manufacture comprising a dry powder or liquid formulation of a drug and at least one protein, wherein the formulation comprises drug nanoparticles , for example matrix-drug nanoparticles wherein the matrix is a protein, such as gelatin (i.e., the drug nanoparticles are packed in a protein), see column 5, lines 46+. The formulation may be for oral administration, etc., see column 5, lines 38+.

Note: the recitation of nanoparticles have been sterilized through a sterilizing filter is a product by process limitation and product by process claims are examined to the extent that they read on the product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 73-75 and 101-104 and 106-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 6,143,276).

Unger discloses composition comprising a drug (bioactive agent) and a stabilizing material, see column 1-2. The stabilizing material may be a protein, such as, albumin, see column 3, lines 5-7. Thus stabilizing material may be combined with a drug to form nanospheres, see column 4, line 62 and column 7, lines 56+. Unger teaches that nanoparticles size provides the advantage of targeted intravascular use, see column 26, lines 30-33. The nanoparticle compositions may be filter sterilized, see column 27. Various drugs may be employed in the nanospheres, including hormones, taxol, anesthetics, etc., see columns 36-37.

Unger fails to specifically disclose (i.e., exemplify) compositions having a protein combined with the same drugs as claimed in nanoparticles size.

It would have been obvious to one of ordinary skill in the art to modify the invention of Unger to arrive at the instant invention because Unger teaches compositions which may have all of the same components, as Unger teaches that proteins, such as, albumins provide a stabilizing effect to various drugs, such as, those claimed and that nanoparticles form of the drug delivery system provides the advantage of targeted intravascular use. Also, Unger teaches that various drugs, including hormones, taxol, anesthetics, etc., may be used as equivalents in the formulations to provide the desired therapeutic effect.

Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Unger as applied to claims 73-75 and 101-104 and above, and further in view of Jones (US 5,731,355).

Unger teaches that the drug may be an anesthetic, but fails to specifically disclose that the anesthetic is propofol.

Jones teaches that propofol is a well-known and highly successful anesthetic, see column 1.

It would have been obvious to one of ordinary skill in the art to use propofol as the anesthetic in the invention of Unger because it is known as a highly successful anesthetic in the art, as shown by Jones.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
June 27, 2003